REMARKS

In the Office Action mailed June 21, 2006, the Examiner objected to the Specification, objected to Claims 9-12, rejected Claims 1-6, 9-13, 15-20, 23, 26-36, 38-40 and 42 under 35 U.S.C. §112(2) for indefiniteness, rejected Claims 9-12 under 35 U.S.C. §101, rejected Claims 1-6, 9-13, 15-20, 23, 26-36, 38-40 and 42 under 35 U.S.C. §112(2) for lacking written description, rejected Claims 1-2, 6, 9-13, 15-16, 18-20, 23, 26-27, 29-35, 38-40 and 42 under 35 U.S.C. §102(b) as being anticipated by WO 01/37654 (hereinafter, "the Tobias application"), and rejected Claims 1-5, 13, 15-20, 23, 26-36, 38-40 and 42 under 35 U.S.C. §102(a) as being anticipated by WO 01/96584 (hereinafter, "the Mushegian application"). Each objection and rejection is addressed below.

I. Objection to the Specification

The Examiner stated, "The disclosure is objected to because of the following informalities: for example, page 34, lines 7 and 26; page 52, line 30; page 53, line 25; page 56, line 8, of the specification contains an embedded hyperlink directed to an Internet address...Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code." Office Action, page 5. The Applicants now amend the Specification so as to remove embedded hyperlinks.

II. Objection to Claims 9-12

These claims have been cancelled, thus the rejection is moot. Applicants reserve the rights to prosecute claims of similar scope in a continuation application and do not believe the objection was proper.

III. Rejection of Claims 1-6, 9-13, 15-20, 23, 26-36, 38-40 and 42 under 35 U.S.C. §112(2)

Claims 1-6, 9-13, 15-20, 23, 26-36, 38-40 and 42 are rejected under 35 U.S.C. §112(2) for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner stated that the claims "are indefinite in the recitation of 'heterologous DNA sequences' which implies two or more DNA sequences. It is unclear if Applicant intends that more than two DNA sequences can be used and can encode 'a

double stranded RNA sequence'. Clarification is required to more clearly define the metes and bounds of the claims." Office Action, pages 3-4.

The Applicants respectfully disagree. However, in order to expedite prosecution while not acquiescing with the Examiner's arguments, Claims 1-3, 6, 15-17, 20, 26, 31-33, 36, 38 and 42 are now amended to specify "a nucleic acid sequence" or double stranded RNA. The Applicants reserve the right to prosecute original Claims 1-3, 6, 15-17, 20, 26, 31-33, 36, 38 and 42 or similar claims at a future date. The Applicants request the rejections be withdrawn.

IV. Rejection of Claims 9-12 under 35 U.S.C. §101

These claims have been cancelled, thus the rejection is moot. Applicants reserve the rights to prosecute claims of similar scope in a continuation application and do not believe the rejection was proper.

V. Rejection of Claims 1-6, 9-13, 15-20, 23, 26-36, 38-40 and 42 under 35 U.S.C. §112(1)

Claims 1-6, 9-13, 15-20, 23, 26-36, 38-40 and 42 are rejected under 35 U.S.C. §112(1) for failing to comply with the written description requirement. In particular, the Examiner stated, "Applicant describes the plant parasitic nematode sequences for H. glycines major sperm protein, RNA polymerase II, and chitin synthase and their use to transform plants by dsRNA to inhibit nematode infection in the plant. These are genus claims...The nucleic acids of the claims are described by function only...Applicant has not described a representative number of nucleic acids encoding dsRNA nematode sequences having nematocidal activity for the production of nematode resistant transgenic plants." Office Action, pages 6-9. The Applicants respectfully disagree.

The Examiner's rejection relies heavily on Eli Lilly and related cases. Office Action, pages 6-7. The Examiner stated "In Eli Lilly...the court stated, 'An adequate written description of DNA 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed invention." Office Action, page 6. Regarding the presently claimed invention, the Examiner concluded, "The nucleic acids of the claims are described by function only." Office Action, page 7.

As a preliminary matter, *Eli Lilly* is not analogous as suggested by the Examiner. Neither the specification nor the claims of the patent addressed by the Federal Circuit in Eli Lilly

contained the sequence for human insulin. Regents of the University of California v. Eli Lilly, 43 USPQ2d 1398 (Fed. Cir. 1997). In the instant case, specific examples of nucleic acids encoding dsRNA nematode sequences having nematocidal activity for the production of nematode resistant transgenic plants is provided throughout the Specification at, for example, Table 2. Table 2 describes numerous nucleic acids encoding dsRNA nematode sequences having nematocidal activity for the production of nematode resistant transgenic plants, and further distinguishes the nucleic acids as, for example, embryonic lethal type, slow growth type, larval death type, molting defect type, paralyzed type, protruding vulva type, sterile type, uncoordinated type, and maternal lethal type. In addition, the Examiner is directed to the Specification at page 33, line 23 through page 34, line 12, which clearly incorporates by reference isolated dsRNA molecules required for nematode embryonic viability. As such, nucleic acids encoding dsRNA nematode sequences having nematocidal activity is provided in the both the specification and the claims and was well known in the art as of the priority date of the application. Thus, applicants have not attempted to define a genus of nucleic acids by only their functional activity. Instead, applicants have disclosed and referred to specific genes. Thus, the analogy the Examiner attempts to draw has no merit.

Moreover, the Examiner's attention is respectfully directed to the Federal Circuit's recent holding in Falkner v. Inglis, 448 F.3d 1357; 79 U.S.P.Q.2D (BNA) 1001 (Fed. Cir. 2006). In that case, the Federal Circuit specifically held that "Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art." Id. at 1367. The Federal Circuit went on to explain that:

> Thus, "[w]hen the prior art includes the nucleotide information, precedent does not set a per se rule that the information must be determined afresh." Id. at 1358. Rather, we explained that:
>
> > The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.
> > Id. at 1357.

> Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in Capon, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." Id. at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification.

Id. at 1367-68. The Federal Circuit then specifically held that "where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences." Id. In the instant case, sequences within the claims were known in the art and reference sequences were described in the specification (see, e.g., Table 2 of the Specification, and the Specification at page 33, line 23 through page 34, line 13) and identified in the claims. That is all the written description that is needed.

As such, one of skill in the art would conclude that the Inventors were in possession of the necessary common attributes possessed by the members of the genus, and therefore the instant specification meets the written description requirement for these claims. The Applicants respectfully request these rejections be withdrawn.

VI. Rejection of Claims 1-2, 6, 9-13, 18-20, 23, 26-27, 29-35, 38-40 and 42 under 35 U.S.C. §102(b)

Claims 1-2, 6, 9-13, 18-20, 23, 26-27, 29-35, 38-40 and 42 are rejected as being anticipated by the Tobias application. In particular, the Examiner stated, "Tobias et al teach methods of inhibition of parasitic nematodes in a plant by transforming the plant with DNA sequences encoding a dsRNA that targets substantially indentical endogenous genes or gene portions." Office Action, pages 10-11.

The Applicants respectfully disagree. However, in order to expedite prosecution while not acquiescing with the Examiner's arguments, the Applicants now amend Claims 1, 15, 26 and 42 to specify that the double stranded RNA sequence targets for genetic inhibition a nematode

embryonic lethal phenotype gene. The Applicants reserve the right to prosecute original Claims 1, 15, 26 and 42, or similar claims, at a later date. The Tobias application does not teach, suggest or describe transgenic plants comprising a double stranded RNA sequence that targets for genetic inhibition a nematode embryonic lethal phenotype gene. The Applicants request these rejections be withdrawn.

The Examiner further states, "Claims 13 and 39 are included in the rejection because no structural characteristics that would distinguish 'a nematode embryonic lethal phenotype gene' from the prior art DNA sequence are recited in the claims or provided in the specification (see at least pages 17-18; 20-22; 28-29; 36-39; and claims on page 40-43)." The Applicants respectfully disagree. As noted above, the Specification provides examples of nematode embryonic lethal phenotype genes within, for example, Table 2 of the Specification wherein specific genes are identified as "EMB" (embryonic lethal phenotype) (e.g., F18C12.2a, T01G9.4, T01G9.5, T01G9.6a, F52B5.6, D1081.8, *dhc-1*), and at page 33, line 23 through page 34, line 13. As such, the Specification does distinguish nematode embryonic lethal phenotype genes over prior art DNA sequences. The Applicants request these rejections be withdrawn.

VII. Rejection of Claims 1-5, 13, 15-20, 23, 26-36, 38-40 and 42 under 35 U.S.C. §102(a)

Claims 1-5, 13, 15-20, 23, 26-36, 38-40 and 42 are rejected under 35 U.S.C. §102(a) as being anticipated by the Mushegian application. In particular, the Examiner stated, "Mushegian et al teach a method of inhibiting nematodes in a plant by transforming the plant with polynucleotide sequences encoding a double stranded RNA or RNAi molecules...The target genes for disruption in the nematode include genes encoding proteins involved in ribosome assembly, transport proteins, protein production, folding and processing, production of polynucleotides...Therefore, Mushegian et al teach all claim limitations." Office Action, pages 11-12.

The Applicants respectfully disagree. However, as noted above, the Applicants now amend Claims 1, 15, 26 and 42 to specify that the double stranded RNA sequence targets for genetic inhibition a nematode embryonic lethal phenotype gene. The Applicants reserve the right to prosecute original Claims 1, 15, 26 and 42, or similar claims, at a later date. The Mushegian application does not teach, suggest or describe transgenic plants comprising a nucleic acid sequence encoding a double stranded nematode RNA sequence, wherein the double

stranded RNA targets for genetic inhibition a nematode embryonic lethal phenotype gene. The Applicants request these rejections be withdrawn.

CONCLUSION

Each rejection of the Office Action mailed June 21, 2006 has been addressed. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: 12-21-06

J. Mitchell Jones
Registration No. 44,174

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
(608) 218-6900